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PROPOSED PETITION DECISION OF THE OCCUPATIONAL SAFETY AND HEALTH STANDARDS BOARD (PETITION FILE NO. 486)

INTRODUCTION

The Occupational Safety and Health Standards Board (Board) received a petition on August 24, 2006, from Mr. Art Pulaski, Executive Secretary-Treasurer, California Labor Federation, and Mr. George Landers, Executive Director, United Food and Commercial Workers, Western States Council (Petitioners). The Petitioners requested that the Board adopt an emergency temporary standard to protect workers from exposure to diacetyl and begin rulemaking proceedings to establish a permanent standard to protect workers from exposure to all food flavorings.

Section 142.2 permits interested persons to propose new or revised standards concerning occupational safety and health, and requires the Board to consider such proposals, and render a decision no later than six months following receipt. Further, as required by Labor Code Section 147, any proposed occupational safety or health standard received by the Board from a source other than the Division must be referred to the Division for evaluation, and the Division has 60 days after receipt to submit a report on the proposal.

SUMMARY

The Petitioners request the Board to immediately issue an emergency temporary standard for diacetyl and begin rulemaking proceedings to establish a permanent standard to protect workers from exposure to all flavorings. The Petitioners state that this action is necessary because exposure to diacetyl has been associated with many cases of severe lung disease among workers in microwave popcorn facilities and in factories where flavorings are produced or used.

The Petitioners state that an emergency standard is needed because workers will continue to be under grave danger of life-threatening illness during the time it would take for the Board to set a permanent standard. Therefore, Petitioners request that the emergency standard should require employers to:

1. Control airborne exposure to diacetyl to below 0.05 parts per million (ppm) averaged over an eight-hour work period, and a ceiling limit should also be set.
2. Provide NIOSH approved respirators for all employees exposed above 0.05 ppm and to employees with any airborne exposure on request.

3. Provide medical surveillance and written notice of the degree of exposure to all employees exposed above 0.05 ppm.
4. Conduct initial and periodic monitoring of airborne exposure to diacetyl.

In addition to the regulatory action requested of the Board, the petition urges CalOSHA to issue immediately a bulletin to all employers and employees potentially exposed to diacetyl, conduct inspections at facilities where workers are exposed to diacetyl, and issue citations where dangerous or uncontrolled exposure occurs. The petition includes an attached statement from 42 prominent occupational health physicians and scientists, which was submitted with the petition filed with Federal OSHA on July 26, 2006, that summarizes the evidence that exposure to diacetyl poses a danger to workers and supports the call for immediate action to prevent irreversible lung disease among diacetyl-exposed workers.

DIVISION'S EVALUATION

The Division's evaluation report dated November 27, 2006, states that based upon the work of National Institute of Occupational Safety and Health (NIOSH) and the Division in flavor using and manufacturing locations respectively, there appears to be little question that serious respiratory illness in the form of bronchiolitis obliterans (BO) has occurred in association with occupational exposure to flavoring substances. Most notable among these substances is diacetyl, which NIOSH has designated as a "marker" for risk of respiratory disease in light of its research findings at the six microwave popcorn plants at which it conducted investigations. In addition diacetyl, at even modest levels of exposure, has also been found to produce serious damage to the respiratory system of animals in short term toxicology studies. Short term toxicology testing of a butter flavor mixture by NIOSH has also reportedly produced respiratory system effects.

Even in the absence of certainty to the causes of the serious cases of respiratory disease associated with occupational exposure to flavoring substances, it is important that an effort be made to address the problem consistent with the best information currently available. That information points to diacetyl as a substance to which worker exposures should be minimized. In addition, in the absence of certainty that diacetyl by itself is the single cause of disease, it is appropriate to attempt to address the risk of developing respiratory disease associated with flavor-related work generally, both at flavor manufacturing locations and at locations which use manufactured flavorings in food production.

The Division, therefore, recommends that the petition be granted to the extent that the Division continue the advisory process with key stakeholders initiated with the meeting on September 28, 2006. The purpose of this process is to further evaluate the nature and extent of the problem of respiratory disease associated with occupational exposure to flavoring substances, and to consider the development of regulatory language to effectively address the problem.

BOARD STAFF'S EVALUATION

Board staff prepared an evaluation dated November 22, 2006, in regards to the Petitioners request for an 8-hour Time Weighted Average (TWA) Permissible Exposure Limit (PEL) of 0.05 ppm for diacetyl (2,3-butanedione) as part of an emergency temporary standard that also would establish a ceiling limit for airborne exposure to diacetyl and include provisions for respiratory protection, medical surveillance, monitoring of airborne exposure to diacetyl, and employee notification when exposure exceeds the PEL. The Petitioners are also requesting the Board to initiate formal rulemaking for permanent standards, which would include provisions similar to an emergency standard, to protect workers exposed to diacetyl and other harmful flavoring-related chemicals.

The Petitioners state that there is strong evidence that BO is caused by exposure to diacetyl and that this evidence comes from workplace studies done by NIOSH, as well as laboratory studies in which animals have been exposed to diacetyl. The petition and the attached supporting letter reference several studies as evidence that the requested standards are necessary. The letter states that data gathered by NIOSH indicate an appropriate emergency PEL would be below 0.2 ppm. In order to provide a sufficient margin of safety, the petition calls for an emergency temporary PEL of 0.05 ppm, averaged over an eight-hour day. The letter further states that although other flavoring-related chemicals are likely to contribute to the adverse lung effects as well, controlling exposure to diacetyl, a known cause of BO and a primary component of butter flavor, will also result in the reduction of exposure to other airborne contaminants in the workplace.

As a basis for the proposed diacetyl PEL, the Petitioners refer to an article by R. Kanwal, et al, which presents findings from an analysis of data from the medical and environmental evaluations NIOSH conducted at six microwave popcorn plants.[1] This article's introductory paragraph summarizes the initial NIOSH studies that indicate exposure to diacetyl is associated with the development of obstructive lung disease, as follows:

"Since August 2000, NIOSH staff have investigated the occurrence of fixed obstructive lung disease consistent with constrictive bronchiolites obliterans in microwave popcorn workers exposed to airborne butter-flavoring chemicals. A NIOSH cross-sectional medical and environmental survey at plant A (the index plant) revealed an elevated prevalence of obstructive lung disease that was associated with cumulative exposure to diacetyl, the predominant butter-flavoring chemical in the air of the plant. In experiments conducted at NIOSH, rats exposed to vapors from a butter flavoring used at this plant developed severe injury of their airway epithelium. Rats developed similar airway damage (although less extensive) with inhalation of vapors of pure diacetyl. These findings implicated butter-flavoring chemicals as a likely etiologic agent for obstructive lung disease in the workers at the index plant. Similar lung disease has also occurred in workers at flavoring-manufacturing plants."

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[1] Kanwal R, et al. Evaluation of flavorings-related lung disease risk at six microwave popcorn plants. *J Occupational environ Med.* 2006; 48(2):149-157. Available at: http://www.defendingscience.org/case_studies/upload/Kanwal.pdf

The Kanwal article further states, "The lowest mean TWA diacetyl air concentrations that we measured in mixing areas (0.02 ppm personal exposure and 0.2 ppm area air concentrations) were at a plant with an affected mixer (plant D); therefore it would seem prudent to maintain worker exposures to diacetyl below these levels." The authors conclude, however, that:

"At this time, insufficient data exist on which to base workplace exposure standards or recommended exposure limits for butter flavorings. Because the risk for occupational lung disease may be partly due to short-term peak exposures, an exposure limit based on an 8-hour TWA may not be sufficient to protect workers. Moreover, because flavorings are complex mixtures of many chemicals, most of which have not been evaluated with respect to inhalation toxicity, focusing solely on diacetyl air concentrations may not be adequate to assess risk in different plants using a variety of different flavorings."

Because entirely safe levels of occupational exposure to butter-flavoring chemicals are not known, the authors recommend the following precautions when producing butter-flavor popcorn:

- Use of closed systems that eliminate the need for workers to handle flavorings in open containers and to open lids of heated tanks to check on their contents.
- Use of local exhaust ventilation on all tanks that are not closed systems.
- Use of isolated rooms under negative air pressure with ventilation separate from the rest of the plant for all flavoring handling and mixing activities and all tanks of heated oil and flavorings that are not closed systems.
- Regularly scheduled medical monitoring with spirometry for detection of declines in lung function that may indicate flavoring-related lung disease in workers who enter the mixing room or perform quality control popping of product in microwave ovens.

The possibility that exposure to flavoring chemicals in the workplace may result in respiratory injury was noted in a 1986 Health Hazard Evaluation published by NIOSH.[2] NIOSH reported that two young, non-smoking, previously healthy employees working in the "mixing room" at a facility that mixed "liquid and powdered flavorings" for use in the baking industry had developed severe, fixed obstructive lung disease within one year of employment. Lung biopsy information from the two workers was not available, but the report concluded that "the clinical picture was more compatible with BO than with emphysema. The report lists diacetyl as one of the common ingredients used in bakery mixes. Dust from the ingredients used in the mixing room was measured in high concentrations in the room air. The investigators concluded that it is probable that some agent in the mixing room produced severe, mixed obstructive lung disease. The report recommended engineering and work practice changes to control respiratory exposure to airborne dust in the mixing room.

Other case reports of severe lung disease associated with the manufacture of food flavoring are noted in a 2004 FEMA publication entitled *Respiratory Health and safety in the Flavor*

[2] NIOSH. Health Hazard Evaluation Report. International Bakers services, Inc. Unpub. Rpt. July 1986. Available at: http://www.cdc.gov/niosh/hhe/reports/pdfs/1985-0171-1710.pdf

Manufacturing Workplace.[3] One case, first reported confidentially to FEMA in 1996 by one of its members, was later the subject of an abstract presented at a medical conference.[4] The abstract reported a case of BO in one worker and an additional four workers with clinical findings consistent with BO. The abstract noted that a comprehensive review of the worksite identified multiple agents as potential causative agents and most prominently acetaldehyde. Additional cases consistent with BO came to light as a result of a confidential incident reporting program FEMA initiated in 2002, which provides flavor manufacturers with the opportunity to report respiratory safety concerns to FEMA and obtain assistance with workplace safety. FEMA's medical consultants found four employees in three companies with reported significant respiratory illness, including a lung biopsy consistent with BO.[4]

The FEMA document lists thirty-four "high priority" chemicals used in flavorings that may have sufficient volatility and reactivity to pose a risk of respiratory injury when associated with certain activities resulting in high exposure levels or repeated exposure at lower levels. FEMA recommends several means of reducing employee exposures to flavorings in regards to: heating of flavors; product substitution; isolating high exposure processes; ventilation; mixing, pouring and packaging activities; storing volatile substances; and cleaning of vessels and work areas. FEMA recommends implementing a respiratory health program oriented around five areas:

1. Management and employee awareness through education and hazard communication.
2. Exposure assessment.
3. Medical surveillance.
4. Material handling strategies and engineering controls for manufacturing, storage, packing and shipping facilities.
5. Personal respiratory protection.

The State of California has undertaken several initiatives in response to reports of respiratory hazards in flavor manufacturing plants in the state. CalOSHA has opened enforcement investigations at two flavor manufacturing plants. The first was inspected and citations with penalties, together with a Special Order, were issued on January 18, 2005. CalOSHA understands that the company has complied with most provisions of the Special Order, including conducting health screening of the employees and implementing exposure control measures.

The second enforcement inspection was opened on April 20, 2006, after a diagnosis of potential BO in an employee was reported to CalOSHA and California Department of Health Services (DHS). DHS and CalOSHA requested assistance from NIOSH to direct the screening of all employees for signs of adverse health reactions to diacetyl and other flavorings and to assist with the evaluation of employee exposures. The screening resulted in a second worker being diagnosed with BO. Citations with penalties, together with a Special Order, were issued in

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[3] *Respiratory Health and Safety in the Flavoring Manufacturing Workplace*, Flavoring and Extract Manufacturers Association of the United States, FEMA, 2004. Available at: http://www.femaflavor.org/html/public/RespiratoryRpt.pdf

[4] Lockey J.E. et al. Bronchiolitis obliterans in the food flavoring manufacturing industry. Abstract presented at the Annual Meeting of the American Thoracic Society, 20 May 2002.

October 2006. A serious citation was issued under Section 5141(a), Control of Harmful Exposures, for failure to implement feasible engineering controls to prevent harmful exposures to hazardous substances, including diacetyl, acetic acid and butyric acid. Under the special order, this employer must implement a respiratory protection plan, submit an exposure control engineering plan, isolate production areas from other areas, enclose mixing tanks to the extent feasible, implement a medical surveillance program, and notify past workers about BO and the risk to them.

As mentioned previously in this proposed decision, CalOSHA initiated a special-emphasis program to target the flavoring manufacturing industry. There are 30 flavoring manufacturers in the state and no popcorn manufacturing plants. As part of the special-emphasis program, employers must contract with private medical and industrial hygiene experts approved by CalOSHA and DHS to conduct respiratory health screening of employees, evaluate exposure to diacetyl and other substance used in the manufacture of flavorings, and implement measure to control employee exposures. More than 224 employees from eight companies have completed at least one round of screening. All screening and hazard evaluation results must be disclosed to CalOSHA and DHS, and abatement measures are subject to their approval. In addition, NIOSH is providing direct assistance in helping CalOSHA to ensure that proper hazard evaluation and control measures are performed at these facilities. DHS distributed bulletins, which contain critical facts on BO and working conditions that may cause it, to healthcare providers, workers, and employers.[5] A bulletin was sent to healthcare providers to help ensure that any lung diseases are correctly diagnosed because there is a concern that physicians may misdiagnose BO as asthma or other more common diseases.

On September 28, 2006, the Division convened a stakeholder advisory meeting to discuss (1) the activities that have occurred to date in California with respect to hazard control in the flavor manufacturing industry, (2) the prospect of rulemaking, including a temporary emergency standard, and (3) how those two agendas can best fit together. At the meeting, staff from CalOSHA, NIOSH, and DHS discussed their organization's activities, answered questions from stakeholders, and generally reiterated and supplemented much of the information previously presented. There was a broad discussion of the issues surrounding the Petitioners' proposal in regards to a PEL for diacetyl, exposure monitoring, medical monitoring, exposure controls, the need for standards, and the scope of proposed standards. No final decision was reached on a regulatory approach to prevent lung injuries in workers in the flavoring industry. Division staff asked the advisory group to provide the Division with proposals to be discussed at the next advisory meeting.

Board staff concludes that the petition has merit. Staff recommends that, because of the complexity of the issues surrounding the petition, the representative advisory committee, convened by the Division, consider the rulemaking issues presented in the petition and, if warranted, develop proposed emergency or permanent standards. The Board has no authority to

[5] *Diacetyl (Butter Flavor Chemical) Use in Flavoring Manufacturing Companies*, Heatlh Hazard Alert, California Dept. Health Services, August 2006. Available at: http://www.dhs.ca.gov/ohb/hesis/diacetyl.pdf

issue a bulletin to all employers and employees potentially exposed to diacetyl, or to conduct inspections at all facilities where workers are exposed to diacetyl, also requested in the petition.

CONCLUSION AND ORDER

The Occupational Safety and Health Standards Board has considered the petition of Mr. Art Pulaski and Mr. George Landers, to adopt an emergency temporary standard to protect workers from exposure to diacetyl, and begin rulemaking proceedings to establish a permanent standard to protect workers from exposure to all food flavorings. The Board has considered the recommendations of the Division and Board staff. The Board has determined that the petition be GRANTED to the extent that the representative advisory committee, which initially was convened by the Division on September 28, 2006, should consider the rulemaking issues presented in the petition and, if warranted, develop proposed language for an emergency and/or permanent standard to be presented to the Board at a future public hearing.